

Claims

1. A lateral flow assay device to test for the presence and/or amount of a nucleic acid sequence of interest in a sample, the lateral flow device comprising:
 - (a) a sample receiving zone for contacting the device with a sample to be tested;
 - (b) an extraction zone for extraction of nucleic acid from the sample;
 - (c) a nucleic acid amplification zone in liquid communication with the sample receiving zone; and
 - (d) a detection zone for detecting the product/s, directly or indirectly, of a nucleic acid amplification reaction performed in the nucleic acid amplification zone, said detection zone being, or being locatable, in liquid communication with the amplification zone.
2. An assay device according to claim 1, wherein the nucleic acid amplification comprises an isothermal amplification reaction.
3. A lateral flow assay device to test for the presence and/or amount of a nucleic acid sequence of interest in a sample, the lateral flow device comprising:
 - (a) a sample receiving zone for contacting the device with a sample to be tested;
 - (b) a nucleic acid isothermal amplification zone in liquid communication with the sample receiving zone; and
 - (c) a detection zone for detecting the product/s, directly or indirectly, of an isothermal nucleic acid amplification reaction performed in the amplification zone, said detection zone being, or being locatable, in liquid communication with the amplification zone.
4. A lateral flow device according to claim 3, further comprising an extraction zone for extraction of nucleic acid from the sample.
5. A lateral flow assay device in accordance with claim 1 and further in accordance with claim 3.

6. A lateral flow assay device in accordance with any one of the preceding claims, wherein the device comprises one or more reagents releasably bound on a porous matrix.
7. A lateral flow assay device according to claim 6, wherein the one or more reagents releasably bound comprise one or more reagents required to perform the nucleic acid amplification reaction.
8. A lateral flow assay device according to any of the preceding claims comprising one or more reagents immobilised on a porous matrix.
9. A lateral flow assay device according to claim 8, wherein the one or more immobilised reagents comprise an amplification-specific capture moiety.
10. A lateral flow assay device according to any one of the preceding claims comprising a releasably bound or an immobilised probe comprising nucleic acid.
11. A lateral flow assay device according to any one of the preceding claims, wherein the sample receiving zone comprises reagents suitable to perform a nucleic acid extraction step on a sample applied to the sample receiving zone.
12. A lateral flow assay device according to any one of the preceding claims comprising dodecyl trimethyl ammonium bromide, FTA paper, or equivalent material.
13. A lateral flow assay device according to any one of the preceding claims, comprising means to cause interruption of flow, alteration of rate of flow, or alteration of flow path, of a liquid along a porous matrix within the device.
14. A lateral flow assay device according to claim 13, comprising means to alter the relative positions of two or more portions of the porous matrix, so as to affect the rate of flow of liquid from one portion to another.

15. A lateral flow assay device according to any one of the preceding claims, wherein the amplification reaction comprises a SMART amplification reaction involving the sequence of interest in the formation of a three way junction with two probe molecules.
16. An assay kit for performing an assay to test for the presence and/or amount of a nucleic acid sequence of interest in a sample, the kit comprising a lateral flow assay device in accordance with any one of the preceding claims and a supply of at least one reagent required to perform the assay.
17. An assay kit according to claim 16, comprising a supply of carrier liquid.
18. An assay kit according to claim 17, wherein said at least one reagent is provided dissolved and/or suspended in the carrier liquid.
19. A method of performing an assay to test for the presence and/or amount of a nucleic acid sequence of interest in a sample, the method comprising the steps of: contacting the sample with the sample receiving zone of a lateral flow assay device in accordance with any one of claims 1-14, so as to cause a nucleic acid amplification reaction in the presence of the sequence of interest; and detecting, directly or indirectly, the product/s of the amplification reaction in the detection zone of the lateral flow assay device.
20. A method according to claim 19, wherein the amplification reaction comprises a SMART amplification reaction involving the sequence of interest in the formation of a three way junction with two probe molecules.
21. A method according to claim 19 or 20, wherein the method comprises the step of performing a nucleic acid extraction step in an extraction zone of the assay device.

22. A method according to claim 21, wherein the extraction step comprises contacting nucleic acid in the sample with dodecyl trimethyl ammonium bromide or "DTAB", and subsequently contacting the extracted nucleic acid/ DTAB mixture with cyclodextrin.
23. A method of making a lateral flow assay device in accordance with the first and/or second aspects of the invention defined above, the method comprising the steps of: forming a porous matrix comprising an amplification zone and a detection zone, said amplification zone being, or being locatable, in liquid flow communication with a sample receiving zone, the sample receiving zone comprising one or more reagents immobilised or releasably bound thereon so as to perform a nucleic acid extraction step on a nucleic-acid containing sample contacted with the sample receiving zone.
24. An assay device substantially as hereinbefore described and with reference to the accompanying drawings.
25. An assay kit substantially as hereinbefore described and with reference to the accompanying drawings.
26. An assay method substantially as hereinbefore described and with reference to the accompanying drawings.